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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,799	04/13/2004	Ferdinand Haschke	88265-16764	3045

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WINSTON & STRAWN
PATENT DEPARTMENT
1400 L STREET, N.W.
WASHINGTON, DC 20005-3502

EXAMINER

TONGUE, LAKIA J

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/822,799

Applicant(s)

HASCHKE ET AL.

Examiner

Lakia J Tongue

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 18 is/are allowed.
- 6) ☐ Claim(s) 1-13, 15-17 and 19 is/are rejected.
- 7) ☐ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed at the EPO on March 1, 2000. It is noted, however, that applicant has not filed a certified copy of the 002007353.9 application as required by 35 U.S.C. 119(b) in the present application or the parent application no. 10/228,722.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 4/13/04 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

Specification

The use of the trademark PREBIO1, RAFTILOSE and RAFTILINE has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claim 14 is objected to because it relies upon a rejected claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2,3, 15-17 and 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of enhancing immune response to the measles virus after a measles vaccination by administering to a subject a prebiotic or nutritional composition, does not reasonably provide enablement for a method of enhancing an immune response by administering a prebiotic to prevent or treat measles before a measles vaccination or for a prebiotic to prevent or treat the measles alone or in combination with a probiotic. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The examiner interprets the claims as a method of enhancing an immune response by giving a prebiotic alone or in combination with a probiotic. Applicant is not enabled for the method wherein at least one prebiotic or nutritional composition comprising at least one prebiotic is administered to a subject for prevention or treatment of measles without administration of a measles vaccination. The specification teaches that an improved immune response did occur

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after the regular consumption of a composition with a prebiotic, but only after a measles vaccination (p.6). Prebiotics and probiotics are known in the art to enhance immune response, however there is no correlation between prebiotics, probiotics or the combination of the two and the treatment or prevention of the measles.

Factors to be considered in determining whether a disclosure would require undue experimentation have been reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CRFC1988). The Wands factors to be considered are:

- a. the quantity of experimentation necessary,
- b. the amount of direction or guidance presented,
- c. the presence or absence of working examples;
- d. the nature of the invention;
- e. the state of the prior art;
- f. the relative skill of those in the art;
- g. the predictability or unpredictability of the art;
- h. breadth of the claims.

The presence or absence of working examples utilizing the administration of a prebiotic alone or in combination with probiotics for the treatment and or prevention of measles are exemplified in the instant specification, however it is not clear that results were obtained as suggested. The prevention and/or treatment of measles were not achieved. The examples provided disclose an immune enhancement, but only after measles vaccination is administered. The quantity of experimentation necessary would be undue for the utilization of any prebiotic or nutritional composition administered to a

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subject for prevention and/or treatment of measles. The specification lacks guidance with respect to the utilization of prebiotics for the treatment and/or prevention of the measles. The amount of direction or guidance presented is minimal in terms of working examples. The nature of the invention involves treatment of the measles with any prebiotic and without any evidence to the contrary, could result in the subject not having protection against measles or treatment of measles, which could result in damage to the patient. The state of the prior art describes the following: Firmansyah, A. et al ("Improved Humoral Immune Response To Measles Vaccine In Infants Receiving Infant Cereal With Fructooligosaccharides", Journal of Pediatric Gastroenterology and Nutrition, 2000; 31) discloses a double-blind randomized controlled study to examine the effects on the immune response after measles vaccination of an infant cereal supplemented with a prebiotic mixture of fructooligosaccharides and inulin. The results concluded that regular consumption of infant cereals with the prebiotic mixture improves immune response after measles vaccination. Agostoni, C. et al (Prebiotic Oligosaccharides in Dietetic Products for Infants: A Commentary by the ESPGHAN Committee on Nutrition, 2004; 39: 465-473) state that future trials should define optimal quantity and types of oligosaccharides with prebiotic function, optimal dosages and duration of intake. Short and long term benefits and safety. At the present time the committee takes the view that no general recommendation on the use of oligosaccharide supplementation in infancy as a prophylactic or therapeutic measure can be made (abstract, page 465). Agostoni et al suggest that the use of prebiotics might lead to increased resistance to pathogens (mainly gastrointestinal tract

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pathogens), modulation of the systematic immune response and of allergic risk, improved bowel function and laxative effects, reduced risk of colon cancer, reduction in cholesterol and blood lipids and enhanced calcium bioavailability and bone mineralization (column 1, page 467). Agostoni et al also disclose that there is no beneficial clinical effect of prebiotics added to infant formulae other than an effect on stool frequency and consistency (column 2, page 467 and column 1, page 468). Agostoni et al conclude that currently there are only limited published data on the evaluation of prebiotic substances in dietetic products for infants. Further, Roberfroid, M. (Prebiotics and probiotics: are they functional foods?, Am J Clin Nutr, 2000; 71: 1682s-7s) claims that inulin-type fructans reduce the risk of disease are only tentative and still need to be supported and validated by further research. The claims include: constipation relief, suppression of diarrhea, reduction risk of osteoporosis, reduction of the risk of atherosclerotic and cardiovascular disease. Cancer is the last area of further research (column 2, page 1684s and column 1, page 1685s). Roberfroid states that the only areas where evidence can be considered promising are diarrhea (probiotics) and constipation (prebiotics) (column 2, page 1685s). Lastly, Roberfroid suggest that the combination of probiotics and prebiotics could beneficially affect the host by improving survival and implantation of live microbial dietary supplements in the gastrointestinal flora and improve the survival of the bacteria crossing the upper part of the gastrointestinal tract (column 1, page 1686s). The relative skill in the art is recognized as high. The breadth of the claims is broad to include oligosaccharide, glucose, galactose, xylose, maltose, sucrose, lactose, starch, xylan, hemicellulose, inulin, or a

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mixture thereof. Therefore, in view of all of the above and in view of the state of the art, it is determined that it would require undue experimentation to use the invention commensurate in scope with the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-6, 8, 9 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavaliere Vesely et al (U.S. Patent 5,895,648, publication 4/20/99).

Claims 1, 4-6, 8, 9 and 11-13 are drawn to a method of enhancing an immune response which comprises administering at least one prebiotic or nutritional composition comprising at least one prebiotic, wherein the prebiotic is present in an amount sufficient to enhance an immune response.

Cavaliere Vesely et al discloses a composition for feed use containing a mixture of lyophilized live bacteria comprising at least two species of bacteria selected from *Bifidobacterium breve*, *Bifidobacterium infantis*, *Bifidobacterium longum*, and *Bifidobacterium bifidum* and at least two species of bacteria selected from *Lactobacillus acidophilus*, *Streptococcus thermophilus*, *Lactobacillus bulgaricus*, *Lactobacillus casei*, *Lactobacillus plantarum* and *Streptococcus faecium* and one or more oligosaccharides

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(abstract). Cavaliere Vesely et al disclose that the present invention is simple, flexible and very useful because it promotes the human organism welfare, promotes synthesis of vitamins and proteins, facilitates digestive processes, prevents colonization and stimulates the immune response (column 7, lines 56-64). Cavaliere Vesely et al disclose that suitable oligosaccharides include oligofructose among others (column 4, lines 53-59). Particularly the appropriate oligosaccharides are inulin and inulin-oligofructose, which are marketed under the names Raftline™ and Raftilose™ (column 4, lines 60-64). Cavaliere Vesely et al further disclose that the present invention may be added to consumables such as liquid, creamy or pasty foodstuffs, products of the milk and dairy industry (milk, milk-based products, milk derivatives) (column 6, lines 55-60). For example, the composition of the present invention can be added to a milk type, yoghurt, or another type of fermented milk, milk based dessert, milk based beverage or a beverage based on milk serum or permeate enriched with fruit, a fruit juice or a beverage based on vegetable extractions (column 6, lines 15-23). The reference differs from the instantly claimed invention because it does not teach the limitation of administering at least one prebiotic. It would have been *prima facie* obvious to a person having ordinary skill in the art at the time the invention was made to administer the composition of Cavaliere Vesely et al to a subject as the prior art suggest placing the composition into a foodstuff, which would be obvious to consume.

Claim 18 is allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Ljt


MARK NAVARRO
PRIMARY EXAMINER